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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,270	05/23/2005	Hidenori Nakajima	260617US0PCT	5020

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EXAMINER	
HAMIDINIA, SHAWN A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/511,270	NAKAJIMA ET AL.	
	Examiner	Art Unit	
	Shawn Hamidinia	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/23/2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *3,6,8-17 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2,4-5,7,18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-2, 4-5, 7 and 18) in the reply filed on September 21, 2005 and SEQ ID NO: 1 filed on December 23, 2005 is acknowledged. Claims 3, 6, 8-17 and 19, are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species.

2. The applicant's traversal is on the grounds that inventions of Group I, II, and IV have unity of invention because they possess the special technical feature of having or recognizing unique structural information. This is not found persuasive because unity of invention shall be fulfilled only when there is a special technical feature which as a whole define a contribution over the prior art. The inventions listed as Groups I and II are directed to polynucleotide sequences and their expressed proteins. These inventions share the common technical feature of a polynucleotide sequence encoding a polypeptide. This common technical feature is not a contribution over the prior art as polynucleotide sequences ID #AK002457 and #AK080857 are deposited and taught by Carninci et al. Thus the invention of Groups I and II lack unity of invention.

The applicant's additional traversal is on the grounds that was based on the inventions of Group I and II, and the screening methods of Groups VI-VII and XII, as being related. This is not found persuasive because of the reasoning discussed in the

previous restriction requirement that described that these groups are **independent and distinct**. Thus, the requirement is still deemed proper and is therefore made FINAL.

Priority

3. The current application filed on May 23, 2005 is a 371 application of PCT/JP03/05431 filed on April 28, 2003 and claims benefit to Japanese application 2002-126107 filed on April 26, 2002.

Information Disclosure Statement

4. The information disclosure statement filed on February 2, 2005 has been considered. Please see the attached initialed PTO-1449s.

Sequence Rule Compliance

5. SED ID NO: I-IV are not compliant with the sequence rule 37 CFR 1.822 (C)(3). Rule 37 CFR 1.822 (C)(3) states that the bases in the coding parts of a polynucleotide sequence shall be listed as triplets (codons). The amino acids corresponding to the codons in the coding parts of a nucleotide sequence shall be typed immediately below the corresponding codons.

Claim Rejections - 35 USC § 112, Second Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1(a), 1(b), 1(c), 1(d), 1(e), 2, 5 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Evidence that claims 1(a)-1(e) fails to correspond in scope with that which applicant regard as the invention can be found in the reply filed December 23, 2005. In

that paper, applicant has stated that they provisionally elected SEQ ID NO: 1, and this statement indicates that the invention is different from what is defined in the claims because SEQ ID NO: 3 and SEQ ID NO: 4 are included in each of these claims.

9. The term "stringent" in claim 1(d) is a relative term which renders the claim indefinite. The term "stringent" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Appropriate correction is required.

10. In claim 2 the applicant uses the term "partial" which is a relative term and renders the claim indefinite. The term "partial" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Appropriate correction is required.

11. Claim 5 depends on itself. Examiner assumes applicant intended the claim to read on "or the vector of claim 4", instead of "or the vector of claim 5". Appropriate correction is required.

12. In claim 18 the applicant uses the phrase "A polynucleotide **of** encoding", this phrase is not clear.

13. In claim 18 the applicant uses the phrase "dominant-negative phenotype". Yet this phrase has not been explained or defined in the specification and is completely unclear how it relates to the invention.

Claim Rejections - 35 USC § 112-Enablement

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claim 1(e) is rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for polynucleotides with 88%, 92%, and 96% identity to the base sequence of SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to

make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404).

Factors to be considered in determining whether a disclosure would require undue experimentation include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In the instant case, (1) the amount of experimentation is large because of the diverse variety of polynucleotides that are encompassed within the 88%, 92%, or 96% sequence identity to SEQ ID NO: 1; a sequence that is 1061 nucleotides in length. Hence, a polynucleotide that has 88% identity allows for 12% of the polynucleotide to vary which would be at least 127 bases. The number of changes this allows is astronomical, all 127 positions could be modified by 3 other polynucleotides alone or in any combination, and the number of corresponding proteins encoded by these polynucleotide sequences would be enormous. (2) Also, there is no guidance provided by the specification on how to use the polynucleotide sequences which are 88%, 92%, or 96% homologous to SEQ ID NO: 1. The specification does not describe how to determine if polynucleotides with 88%, 92%, or 96% sequence identity to SEQ ID NO: 1 still have functional activity, in particular, whether or not they retain their functional involvement in sugar production. Further, (3) the specification is totally devoid of any

working examples of polynucleotides which is more than 88% homologous to SEQ ID NO: 1. The specification merely describes that SEQ ID NO: 2, a 35 kd human protein, binds to substance WF00144; As for the next Wands factor, (4) the nature of the invention is polynucleotides having at least 88%, 92%, or 96% sequence identity to SEQ ID NO: 1. There is no prior art (5) to the polynucleotides having between 88% to 96% sequence homology to SEQ ID NO: 1; (6) the relative level of skill in this art is very high; (7) the predictability of the art is low with regard to the determination of the function of any of these polynucleotides and the polypeptides they encode, and further it is unknown whether they retain their involvement in sugar production. Finally, (8) the claims are extremely broad because 88% sequence homology is claimed and all of the species of encompassed by this sequence identity are completely undefined and uncharacterized.

Based on this analysis, the conclusion that it would require undue experimentation to practice the instant invention is inescapable.

Claim Rejections - 35 USC § 112-Enablement

16. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

17. Claims 1(c) and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for a polynucleotide encoding

an amino acid sequence of SEQ ID NO: 2 where one or a few amino acids are substituted, deleted, inserted and/or added and which have a dominant-negative phenotype to the protein that comprises SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404).

Factors to be considered in determining whether a disclosure would require undue experimentation include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In the instant case, (1) the amount of experimentation is large because an enormous variety of polypeptide sequences encompass an amino acid sequence of SEQ ID NO: 2, a polypeptide sequence about 327 amino acids in length, where one or more amino acids are substituted, deleted, inserted and/or added. Hence, the claim as written reads on a polypeptide that has two amino acids changed, inserted, or deleted anywhere within the polypeptide sequence. The number of changes this allows is astronomical (any position in the protein could be modified/altered). (2) Also, there is no guidance provided by the specification on how to use the polypeptides which have been randomly mutated. The specification does not describe how to determine if polypeptides with random mutations still have functional activity, in particular, whether or not they retain their presumed role in sugar production. Further, the specification does not describe at all how to determine what changes and where in the polypeptide sequence would result in a "dominant-negative phenotype". Moreover, (3) the specification is totally devoid of any working examples of randomly mutated polypeptides. The specification merely compares SEQ ID 2, a 35 kd human protein, and its binding to substance WF00144 and; As for the next Wands factor, (4) the nature of the invention is polypeptides having random mutations of SEQ ID NO: 2. There is prior art (5) to the polypeptides of having more than 90% sequence homology to SEQ ID NO:2; (6) the relative level of skill in this art is very high; (7) the predictability of the art is low with regard to the determination of the function of any of these polypeptides and whether they retain their functional properties, particularly their involvement in sugar production. Finally, (8) the claims are extremely broad because the random

mutations of SEQ ID NO: 2 as claimed and all of the species of encompassed by this sequence identity are completely undefined and uncharacterized.

Based on this analysis, the conclusion that it would require undue experimentation to practice the instant invention is inescapable.

Claim Rejections - 35 USC § 112, First Paragraph-Written Description

18. Claim 1(e) is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polynucleotide sequence with 88%, 92%, and 96% identity to the base sequence of SEQ ID NO: 1.

The claimed invention does not meet the current written description requirements for the following reasons. Firstly, substantial variation in structures and functions are expected among polypeptides that share 88% sequence identity to SEQ ID NO: 1. Further, the disclosure of SEQ ID NO: 1 does not provide adequate written description for all polynucleotides having at least 88%, 92%, or 96% sequence identity to SEQ ID NO: 1. Since Applicant does not have any representative examples of a single species of the polynucleotides of claims 1(e), the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms. Given this lack of

disclosure, Applicant's written description of the claimed invention is insufficient to show that Applicants were in possession of the full scope of the claimed invention.

Claim Rejections - 35 USC § 112, First Paragraph-Written Description

19. Claim 1(c) and 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a polynucleotide encoding an amino acid sequence of SEQ ID NO: 2 where one or a few amino acids are substituted, deleted, inserted and/or added and which have a dominant-negative phenotype to the protein that comprises SEQ ID NO: 2.

The claimed invention does not meet the current written description requirements for the following reasons. Firstly, substantial variation in structures and functions are expected among polypeptides that have been randomly mutated with one or more amino acids at various portions of the protein sequence of SEQ ID NO: 2. Secondly, claim 18 provides claim to polypeptide sequences with random mutations at one or more amino acids of SEQ NO: 2 which result in a dominant-negative phenotype to the protein that comprises the amino acid sequence of SEQ ID NO: 2. Yet there is no support for the claimed invention, including how one could determine if a substitution, deletion, insertion, and/or addition resulted in a dominant-negative phenotype to the

polypeptide sequence of SEQ ID NO: 2. Lastly, the disclosure of the 35 kd protein does not provide adequate written description for all polypeptides where one or a few amino acids are substituted, deleted, inserted and/or added in SEQ ID NO: 2. Since Applicant does not have any representative examples of a single species of the polypeptides of claims 1(c) and 18, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms. Given this lack of disclosure, Applicants' written description of the claimed invention is insufficient to show that Applicants were in possession of the full scope of the claimed invention.

Claim Rejections - 35 USC § 102

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

21. Claim 1(a), 1(b), 1(c) 1(e) is rejected under 35 U.S.C. 102(a) and (e) as being clearly anticipated by Tang et al. and Strausberg et al.

Tang et al. (US 60/336,453) disclose a polynucleotide sequence (sequence 103) with 96.6% sequence identity to the elected polynucleotide of the invention designated as SEQ ID NO:1. This clearly anticipates claims claims 1(a) and 1(e) under 102(e).

Tang et al. (US 60/336,453) disclose a polynucleotide sequence encoding a protein that comprises an amino acid sequence of SEQ ID NO: 2 with 99.6% sequence identity to the peptide of the invention designated as SEQ ID NO: 2. This clearly anticipates claim 1(b) and 1(c) under 102(e).

Stausberg et al. (2002) disclose a polynucleotide sequence (accession BC045550) with 96.6% sequence identity to the elected polynucleotide of the invention designated as SEQ ID NO:1. This clearly anticipates claims claims 1(a) and 1(e) under 102(a).

Strausberg et al. (2002) disclose a polynucleotide sequence encoding a protein that comprises an amino acid sequence of SEQ ID NO: 2 with 100% sequence identity to the elected peptide of the invention designated as SEQ ID NO: 2. This clearly anticipates claim 1(b) under 102(a).

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

Claim Rejections - 35 USC § 102

22. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

23. Claims 2 and 7 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Valenzuela et al. (2000).

Claim 2 as reads on glycine.

Valenzuela et al. (2000) disclose a polynucleotide sequence (accession AAA93103) with 100% sequence identity to the base sequence complementary to the elected polynucleotide of the invention designated as SEQ ID NO:1, and having at least 19 bases. This clearly anticipates claims claim 7 under 102(b).

Conclusion

24. No claims are allowed.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawn Hamidinia whose telephone number is (571) 272-4534. The examiner can normally be reached on Mon-Fri from 9:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SAH

ROBERT A. WAX
PRIMARY EXAMINER